

**REMARKS**

Claims 1-7, 9-20 and 22 are currently pending in the subject application, and are presently under consideration. Claims 1-3, 8-16, 21 and 22 are rejected. Claims 4-7 and 17-20 have been indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1, 2, 4, 9, 10, 14, 15 and 22 have been amended and claims 8 and 21 have been cancelled.

Favorable reconsideration of the application is requested in view of the amendments and comments herein.

**I. Claim Objections**

Claim 15 has been amended to depend from claim 14. Withdrawal of the objection to claim 15 is respectfully requested.

**II. Rejection of Claims 18-11, 13-15 and 21-22 Under 35 U.S.C. §102(b)**

Claims 1, 8-11, 13-15 and 21-22 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5258,023 to Reger ("Reger"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

Claim 1 has been amended to incorporate the subject matter from claim 8. Accordingly, claim 1 now recites that the support is positioned around the sidewall portion of valve member intermediate the inflow end and the outflow end of the valve member, such that an inflow end of the support is spaced apart from the inflow end of the valve member and an outflow end of the support is spaced apart from the outflow end of the valve member. The Office Action contends that the subject matter recited in original claim 8 (now in amended claim 1) is disclosed with respects to Figs. 21 and 22 of Reger. Applicant respectfully disagrees with this contention. Specifically, Fig. 21 of Reger depicts a valve that is sewn into a stent to form an aortic valve prosthesis in which the valve is in a nearly opened configuration, while Fig. 22 illustrates a perspective view of the same aortic valve rotated about a vertical axis and in a closed configuration. Reger at column 7, lines 10 – 15. Moreover, the Office Action identifies the support stent 30 taught by Reger as corresponding to the support recited in claim 1. However, as shown and described with respect to Figs. 14 – 16 of Reger, the heart valve apparatus 20 is

positioned within the stent 30, but the stent 30 is not positioned intermediate the inflow and outflow ends of the valve apparatus 20 in the manner recited in amended claim 1. In sharp contrast, the prostheses shown and described in the various embodiments of Reger have the stent apparatus 30 extending beyond (not between) the inflow and outflow ends of the valve apparatus 20.

The Office Action also appears to allege that the stent portion 30 corresponds to a covering over the radially outer exposed surface of at least the strip, as recited in claim 1. Clearly, the stent 30 does not extend over the interfacing portion 104.

Since Reger fails to teach the subject matter recited in amended claim 1, amended claim 1 is patentable over Reger. Reconsideration and allowance of amended claim 1 are respectively requested.

Claims 2-3, and 9-12 are patentable for at least the same reasons that amended claim 1 is patentable. Claim 9 has been amended to depend from amended claim 1 and to correct an inadvertent typographical error.

Additionally, claim 10 has been amended to recite that the outflow extensions extend axially beyond and lateral each of a plurality of commissures proximal an outflow end of the valve member. The Office Action refers to Figs. 21 and 22 in its rejection of claim 10. However, there is nothing shown in Figs. 21 and 22 that would correspond to the outflow extensions as recited in amended claim 10. Accordingly, reconsideration and allowance of amended claim 10 are respectfully requested.

Claim 11 depends from claim 10 and further recites a sheath of flexible material that covers the support and at least a substantial portion of an exterior part of the sidewall of the valve member, the outflow extensions being formed of outflow extending portions of the sheath that extend a predetermined distance beyond each of the plurality of commissures proximal the outflow of the valve member. Again, nothing shown nor described with respect to Figs. 21 and 22 or elsewhere in Reger would correspond to the sheath and the outflow extensions that are formed as outflow extending portions of such sheath. Accordingly, applicant respectfully requests reconsideration and allowance of claim 11.

Claims 14 and 15 should be patentable for at least the same reasons discussed above with respect to claims 10 and 11, respectively.

Claim 22 has been amended into independent form, and claim 21 from which claim 22 depended has been cancelled. Significantly, the Office Action has identified no structure that might correspond means for inhibiting inward deflection of commissures at an outflow end of the sidewall portion of the valve means when attached to surrounding tissue, as recited in claim 22. Applicant submits the omission of identifying any such structure is because no such structure in the Office Action is shown or described in Reger. Nonetheless, claim 22 is patentable for similar reasons to those discussed with respect to claim 10.

### **III. Rejection of Claims 2, 3, 12 and 16 Under 35 U.S.C. §103(a)**

Claims 2, 3, 12 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Reger. Withdrawal of this rejection is respectfully requested for at least the following reasons.

The Office Action contends that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the synthetic material of the Reger reference with the material properties of applicant's invention. However, such statement directly contradicts the express teachings of Reger. For example, at column 2, lines 39-54, Reger teaches that there are problems associated with various tissue type valves. Moreover, in the brief summary and objects of the invention section of the Reger reference makes the express statement that, "The invention is a long lasting implantable prosthetic heart valve which contains no tissue component." Reger at column 3, lines 4-6. Since Reger expressly teaches that its prosthetic heart valve contains no tissue component, contrary to the position in the Office Action, it would not have been obvious to one of ordinary skill in the art to modify Reger to have the material properties recited in claims 3 and 12. That is, Reger expressly teaches and requires that there be no tissue components in its prosthesis, such that the subject matter in claims 3 and 12 would not be obvious to one of ordinary skill in the art in view of the teachings of Reger.

For these reasons and for the reasons discussed with respect to claim 1, applicant respectfully request reconsideration and allowance of claims 2, 3, 12 and 16.

**IV. Allowable Subject Matter**

Applicant appreciates the indication that claims 4 – 7 and 17 – 20 contain allowable subject matter, and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In this regard, Applicant has amended claim 4 into independent form and, therefore, requests allowance of claims 4-7.

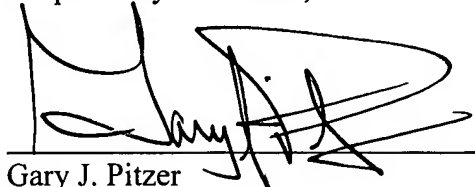
**V. CONCLUSION**

In view of the foregoing remarks, Applicant respectfully submits that the present application is in condition for allowance. Applicant respectfully requests reconsideration of this application and that the application be passed to issue.

If the Examiner has any questions or if the Applicant or its representative can be of any assistance in connection with prosecution of this application, the Examiner is invited and encouraged to contact the undersigned at the number identified below.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,



Gary J. Pitzer  
Registration No. 39,334

CUSTOMER No.: 26,294

TAROLLI, SUNDHEIM, COVELL, & TUMMINO L.L.P.  
1300 EAST NINTH STREET – SUITE 1700  
CLEVELAND, OHIO 44114  
Phone: (216) 621-2234  
Fax: (216) 621-4072